

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

ATHENA DIAGNOSTICS, INC., THE  
UNIVERSITY OF CHICAGO and  
CORRELAGEN DIAGNOSTICS, INC.,

Plaintiffs,

v.

AMBRY GENETICS CORPORATION,

Defendant.

C.A. No. 4:09-CV-40201-FDS

**DEFENDANT AMBRY GENETICS CORPORATION'S  
ANSWER TO PLAINTIFFS' AMENDED COMPLAINT**

Defendant Ambry Genetics Corporation (“Ambry” or “Defendant”) states the following as its Answer to Plaintiffs’ Amended Complaint (“Amended Complaint”) filed by Plaintiffs Athena Diagnostics, Inc., The University of Chicago and Correlagen Diagnostics, Inc. (collectively “Plaintiffs”):

**Parties, Jurisdiction and Venue**

1. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Complaint, and therefore, denies them.
2. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and therefore, denies them
3. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, and therefore, denies them
4. Defendant admits the allegations of paragraph 4.

5. Defendant responds that the statements in paragraph 5 of the Complaint state legal conclusions to which no response is required. To the extent that a response is required, Defendant denies that it has committed any acts of patent infringement.

6. Defendant responds that the statements in paragraph 6 of the Complaint state legal conclusions to which no response is required. To the extent that a response is required, Defendant denies that venue is proper or convenient.

**Facts Giving Rise to Claims Against Ambry**

7. Paragraph 7 is a characterization and contains no allegations of fact to which an answer is required. To the extent a response is required, Defendant denies the allegations of paragraph 7.

8. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 8 and therefore denies them.

(a) Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 8(a) and therefore denies them.

(b) Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 8(b) and therefore denies them.

(c) Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 8(c) and therefore denies them.

9. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 9 and therefore denies them.

10. Defendant admits that U.S. Patent No. 6,187,533 (the “‘533 patent”) indicates that the United States Patent and Trademark Office issued the ‘533 patent on February 13, 2001. Defendant denies the remaining allegations of paragraph 10.

11. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 11 and therefore denies them.

12. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 12 and therefore denies them.

13. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 13 and therefore denies them.

14. Defendant is without information or belief sufficient to form a belief as to the truth of the allegations of paragraph 14 and therefore denies them.

15. Defendant denies the allegations of paragraph 15.

16. Defendant denies the allegations of paragraph 16.

17. Defendant denies the allegations of paragraph 17.

### **AFFIRMATIVE DEFENSES**

#### **First Affirmative Defense** **(Non-infringement)**

Defendant has not infringed, either literally or under the doctrine of equivalents, nor contributed to the infringement by others, nor induced others to infringe, any valid claim and enforceable claim of the '533 patent.

#### **Second Affirmative Defense** **(Patent Invalidity)**

Defendant is informed and believes, and based thereon alleges, that one or more claims of the '533 patent are invalid by failing to satisfy one or more of conditions of patentability set forth in the Patent Act, 35 U.S.C. § 100, *et seq.*, including but not limited to Sections, 101, 102, 103, and/or 112.

**Third Affirmative Defense**  
**(Lack of Personal Jurisdiction)**

This Court lacks personal jurisdiction over Defendant.

**Fourth Affirmative Defense**  
**(Lack of Standing)**

Plaintiffs lack standing to bring this action.

**Fifth Affirmative Defense**  
**(Failure to State a Claim)**

Plaintiff fails to state a claim upon which relief may be granted.

**Sixth Affirmative Defense**  
**(Laches, Waiver, Acquiescence, Estoppel)**

Plaintiffs' claim is barred, in whole or in part, from seeking any relief because of laches, waiver, acquiescence, and/or estoppel.

**Seventh Affirmative Defense**  
**(Improper Venue)**

Venue is improper in this District pursuant to 28 U.S.C. § 1400(b) and pursuant to 28 U.S.C. § 1401(a), the convenience of the Defendant and witnesses and the interest of justice, venue is more appropriate in another district.

**Eighth Affirmative Defense**

Any additional defenses or counterclaims that discovery may reveal.

**Answer to Plaintiffs' Prayers for Relief**

WHEREFORE, Defendant denies that Plaintiffs are entitled to any relief whatsoever from Defendant, as prayed for or otherwise. Accordingly, Plaintiffs' Amended Complaint should be dismissed in its entirety and with prejudice, the relief requested by Plaintiffs should be

denied, and Defendant should be awarded its costs and fees of this action, as well as such further and other relief that the Court may deem just and equitable.

### **COUNTERCLAIMS**

#### **The Parties**

1. Ambry Genetics Corporation (“Ambry”) is a corporation organized under the laws of the State of California, having its principal place of business at 100 Columbia, Suite 200, Aliso Viejo, California 92656.

2. On information and belief, Athena Diagnostics, Inc., (“Athena”) is a corporation duly organized under the laws of the State of Delaware, having a principal place of business at Four Biotech Park, 377 Plantation Street, Worcester, Massachusetts 01605.

3. On information and belief, The University of Chicago (“Chicago”) is a not-for-profit corporation organized under the laws of the State of Illinois with a principal place of business at 5801 South Ellis Avenue, Chicago, Illinois, 60637.

4. On information and belief, Correlagen Diagnostics, Inc., (“Correlagen”) is a corporation organized under the laws of the Commonwealth of Massachusetts having a principal place of business at 307 Waverly Oaks Road, Waltham, Massachusetts, 02452.

### **JURISDICTION AND VENUE**

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Athena, Chicago and Correlagen (collectively “Counterclaim Defendants”) at least for the reasons that each has either a principal

place of business within this judicial District or has submitted to the jurisdiction of this Court by suing Ambry in this judicial District.

8. Venue is proper in this judicial district because these claims are being brought as compulsory counterclaims pursuant to Fed. R. Civ. P. 13(a), and under 28 U.S.C. §§ 1391(b) and (c) and because the claims set forth herein involve federal questions of United States patent law.

### **BACKGROUND**

9. U.S. Patent No. 6,187,533 (the “‘533 patent”), entitled “Mutations in the Diabetes Susceptibility Genes Hepatocyte Nuclear Factor (HNF) 1 Alpha( $\alpha$ ), HNF1 $\beta$  and HNF4 $\alpha$ ,” was issued by the United States Patent and Trademark Office on February 13, 2001. Arch Development Corporation is listed as the assignee on the face of the ‘533 patent.

8. Ambry is a well-respected advanced genetic testing company.

9. Ambry assists physicians, patients and researchers with comprehensive, reliable and state-of-the-art DNA diagnostic testing for a multitude of important diseases including Cystic Fibrosis, Diabetes, pancreatic and other pulmonary diseases.

### **THE CONTROVERSY**

10. On November 18, 2009, Counterclaim Defendant Athena Diagnostics individually filed the original complaint in this action against Ambry alleging that Ambry has infringed the ‘533 patent (“Complaint”).

11. On March 15, 2010, Counterclaim Defendants filed the current Amended Complaint against Ambry alleging that Ambry has infringed the ‘533 patent.

12. Counterclaim Defendants allege in the Amended Complaint that they have the right to initiate infringement actions with respect to the ‘533 patent.

13. Counterclaim Defendants also allege in the Amended Complaint that “Ambry has performed, and is continuing to perform the HNF4 $\alpha$ , HNF1 $\alpha$ /TCF1 and HNF1 $\beta$ /TCF2 EMMD tests for the diagnosis of MODY 1, MODY 3 and MODY 5 in the United States, and Ambry has thereby infringed, and is continuing to infringe, the ‘533 Patent, directly and/or by active inducement and/or by contributory infringement, including infringement in this District.”

14. Ambry denies all allegations of infringement of the ‘533 patent and reserves the right to assert invalidity of the ‘533 patent for failure to comply with one or more the conditions of patentability in the Patent Act, 35 U.S.C. § 100, *et seq.*, including but not limited to Sections, 101, 102, 103, and/or 112.

15. Based on the foregoing, there is an actual and immediate controversy between Ambry and Counterclaim Defendants concerning whether Ambry has infringed the ‘533 patent and whether that patent is valid and enforceable.

**FIRST CLAIM FOR RELIEF**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ‘533 PATENT)**

16. Ambry restates all of the foregoing paragraphs of its counterclaims as if set forth specifically herein.

17. Ambry’s method of diagnostic testing does not literally infringe any valid claim of the ‘533 patent.

18. Ambry’s method of diagnostic testing does not infringe any valid claim of the ‘533 patent under the Doctrine of Equivalents.

19. Ambry’s method of diagnostic testing does not infringe indirectly, and will not infringe indirectly, any valid claim of the ‘533 patent.

**SECOND CLAIM FOR RELIEF**  
**(DECLARATION OF INVALIDITY OF THE '533 PATENT)**

20. Ambry restates all of the foregoing paragraphs of its counterclaims as if set forth specifically herein.

21. The '533 patent, and each claim thereof, is invalid for failing to comply with one or more of the conditions of patentability in the Patent Act, 35 U.S.C. § 100, *et seq.*, including but not limited to Sections, 101, 102, 103, and/or 112.

**PRAYERS FOR RELIEF**

WHEREFORE, Ambry prays for the entry of a judgment in Ambry's favor by granting the following relief:

- A. Dismissing with prejudice all of Plaintiffs' claims against Ambry in its entirety and with prejudice;
- B. Denying the relief sought by Plaintiffs in the Amended Complaint;
- C. Declaring that Ambry's method of diagnostic testing does not and will not infringe, literally, under the Doctrine of Equivalents or indirectly, any valid claim of the '533 patent;
- D. Declaring that the '533 patent, and each claim contained therein, is invalid;
- E. Enjoining Plaintiffs and their officers, agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice from threatening or alleging that Ambry or its present or prospective customers, dealers or suppliers, infringe the '533 patent, or initiating litigation against any such entities for infringement of the '533 patent;
- F. Declaring that this is an "exceptional" case within the meaning of 35 U.S.C. § 285, and awarding Ambry its reasonable attorneys' fees, costs and expenses in this action;



G. Awarding Ambry such other and further relief as the Court deems just and equitable.

COOLEY GODWARD KRONISH, LLP

/s/Richard S. Sanders

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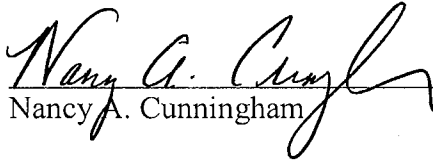
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Attorneys For Defendant,  
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Dated: April 15, 2010

**CERTIFICATE OF SERVICE**

I, Nancy A. Cunningham, hereby certify that pursuant to Local Rule 5.4(C), this documents has been filed through the ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF). For those parties indicated as non-registered participants a paper copy will be sent by facsimile and/or U.S. First Class Mail on April 15, 2010

  
Nancy A. Cunningham